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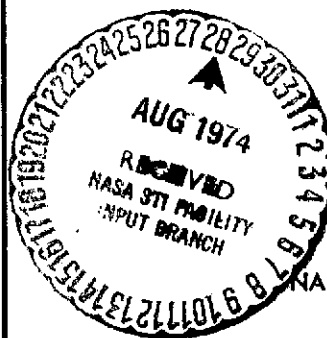


TOPOGRAPHY OF AORTIC HEART VALVES

(NASA-CR-139566) TOPOGRAPHY OF AORTIC
HEART VALVES Final Report (Illinois
Univ.) 38 p HC
CSCL 06P

Final Technical Report
February 1, 1972-August 1, 1974

By
H. M. KARARA



A Study Sponsored By
NASA-LYNDON B. JOHNSON SPACE CENTER
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BIBLIOGRAPHIC DATA SHEET		1. Report No.	2.	3. Recipient's Accession No.	
4. Title and Subtitle Topography of Aortic Heart Valves				5. Report Date August 1, 1974	
				6.	
7. Author(s) H. M. Karara				8. Performing Organization Rept. No. UIIU-ENG-74-2017	
9. Performing Organization Name and Address Department of Civil Engineering University of Illinois at Urbana-Champaign Urbana, Illinois 61801				10. Project/Task/Work Unit No.	
				11. Contract/Grant No. NAS 9-12459	
12. Sponsoring Organization Name and Address NASA-Lyndon B. Johnson Space Center Houston, Texas 77058				13. Type of Report & Period Covered Final Report 2-1-72 to 8-1-74	
				14.	
15. Supplementary Notes					
16. Abstracts The work conducted under this contract is a part of a cooperative effort between the Department of Civil Engineering of the University of Illinois at Urbana-Champaign and the Department of Civil and Environmental Engineering of Washington University, St. Louis, Missouri, on the development of a tri-leaflet prosthetic heart valve. The work at Washington University has been sponsored by the National Institute of Health, Grant No. R01-HE-13803-01. The photogrammetric studies were conducted on silicone rubber molds. Information on data acquisition and data reduction phases is given in this report. Accuracy aspects of the project are discussed and the various outputs (digital models, profiles, contour maps, etc.) are reviewed.					
17. Key Words and Document Analysis. 17a. Descriptors Photogrammetry Bioengineering Heart Valves Mapping					
17b. Identifiers/Open-Ended Terms Close-Range Photogrammetry Biomedical Research, Bioengineering Contour Mapping Digital Models					
17c. COSATI Field/Group 08/02, 06/03					
18. Availability Statement Release Unlimited Thru NTIS				19. Security Class (This Report) UNCLASSIFIED	21. No. of Pages 36
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TOPOGRAPHY OF AORTIC HEART VALVES

Final Technical Report
February 1, 1972-August 1, 1974

by

Dr. H. M. Karara
Principal Investigator

A Study Sponsored By

NASA-LYNDON B. JOHNSON SPACE CENTER
Houston, Texas 77058

Contract No. NAS 9-12459

Department of Civil Engineering
University of Illinois at Urbana-Champaign
Urbana, Illinois 61801

August 1974

FOREWORD

This report was prepared as a part of the research work on the Development of a Tri-Leaflet Aortic Valve Prosthesis, sponsored by NASA-Lyndon B. Johnson Space Center (Contract No. NAS 9-12459).

The author wishes to thank Mr. M. J. Bender, contract monitor Dr. P. L. Gould and Dr. R. E. Clark, Washington University, St. Louis, who all contributed significantly to the progress of the investigation by their helpful suggestions and comments. The valuable assistance rendered by Messrs. G. T. Marzan, V. D. Brandow, and R. R. Kairam, Research Assistants in Civil Engineering at the University of Illinois, is gratefully acknowledged.

This final report covers the period from February 1, 1972 to August 1, 1974.

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ABSTRACT

The work conducted under this contract is a part of a cooperative effort between the Department of Civil Engineering of the University of Illinois at Urbana-Champaign and the Division of Cardiothoracic Surgery and the Department of Civil and Environmental Engineering of Washington University, St. Louis, Missouri, on the development of a tri-leaflet prosthetic heart valve. The work at Washington University has been sponsored by the National Institute of Health, Grant No. R01-HE-13803-01. The photogrammetric studies were conducted on silicone rubber molds. Information on data acquisition and data reduction phases is given in this report. Accuracy aspects of the project are discussed and the various outputs (digital models, profiles, contour maps, etc.) are reviewed.

1. INTRODUCTION

The aortic valve is a one-way check valve between the left ventricle of the heart and the aortic artery, as sketched in Fig. 1. The valve is composed of three approximately crescent-shaped leaf-

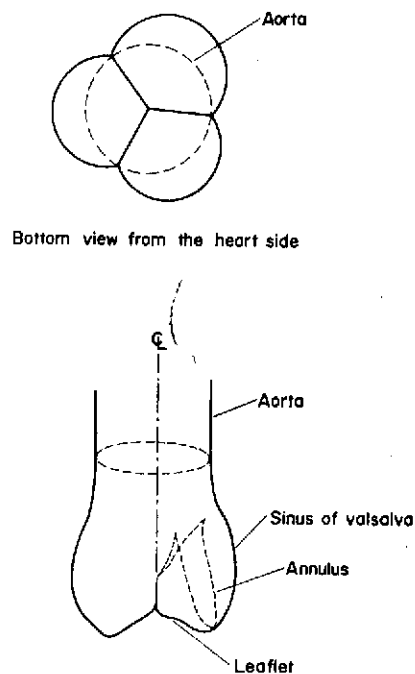


Fig. 1 - Aortic Valve Configuration -- After Gould et al. (4).

lets. As the heart pumps, the tri-leaflet aortic valve opens and closes, thus allowing the blood to flow from the left ventricle during the ejection (systolic) stage, and preventing fresh blood from backing up into the left ventricle in the filling (diastolic) stage. During the systolic stage, the three leaflets fold back toward the

wall of the aorta, thus opening the valve. In the diastolic stage, the leaflets come together, thus closing the valve. When the natural valve is damaged by disease, such as rheumatic fever, or injury, it does not close properly, thus decreasing the heart's efficiency. To rectify this situation, the damaged aortic heart valve is replaced by a synthetic valve.

Prosthetic heart valves, of various types and designs, have been in use for some time. Tens of thousands of people have had their aortic heart valve replaced. Synthetic valves used so far require the continual use of anti-coagulants which can have undesirable side effects.

Since some four years ago, a multi-disciplinary research team headed by R. E. Clark, M. D., of the Division of Cardiothoracic Surgery, Washington University, St. Louis, has been working on the development of a new prosthetic tri-leaflet aortic heart valve which is an improvement over valves used currently. This research team is composed of professionals from a number of disciplines including cardiothoracic surgery, structural engineering, fluid mechanics materials, computer science and photogrammetry.

The proposed prosthetic valve will be a central flow device, just as the actual human valve, rather than the current central occluding devices which have less than satisfactory hydrodynamics with resultant blood degradation and thromboembolic phenomena.

An overview of the various studies involved in the total project were summarized by Clark et al. (3): "A complete multi-phasic study has been performed which involved (1) the careful definition of the normal anatomy of leaflets, including the surface characteristics, thickness variations, and composite nature of the internal structure; (2) uniaxial stress-strain data on leaflet tissue discerned the anisotropic and nonlinear behavior in the very low stress region; (3) a numerical-graphic analysis of the opening characteristics of the aortic valve detailed the magnitude and relations of bending, shear, and loading stresses; (4) a detailed analysis of the distribution of in-plane stresses was made through the use of close range stereophotogrammetry which defined the asymmetric shell surfaces in global coordinates; (5) a computer-based finite element method of analysis was used to obtain the principal stress resultants over a physiologic pressure range; (6) ultra-pure polyester resin was made and extruded into 10 μ fibers and woven into a multilayered fabric to yield variation in thickness, mechanical behavior and surface characteristics superior to previous devices. The rationale and durability aspects of this project will be discussed."

An accurate assessment of the geometry of human aortic heart valves is necessary to develop the configuration of the synthetic heart valve and determine the necessary strength and elasticity for the synthetic fabric, which is of a gauze-like structure, to with-

stand the pressures to which the prosthetic valve will be subjected in the human body.

Since the maximum stress on the heart valve is induced when the valve is closed and subject to diastolic pressure, it was decided to determine the valve geometry during diastole. Because the actual valves could not be measured, molds of freshly exised human aortic valves were used instead. A typical heart valve mold is shown in Fig. 2. The molds were formed by pouring a silicon rubber material into the exised aorta, thus causing the valve to close.

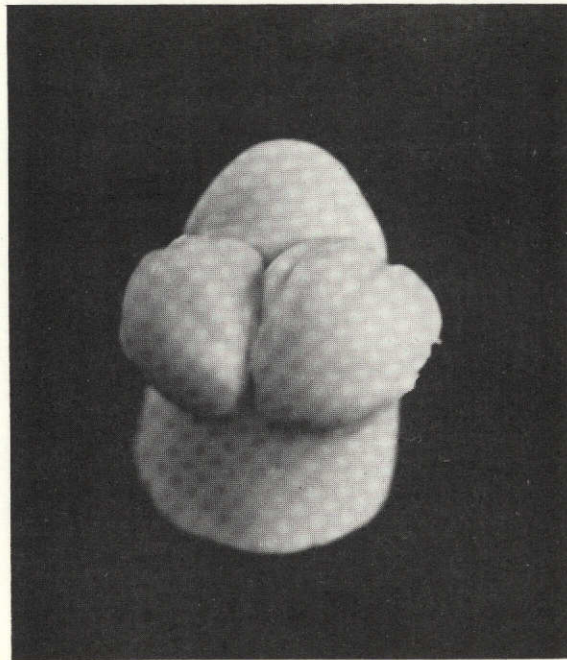


Fig. 2 - A Typical Heart Valve Mold

This way, the molds accurately represented the topography of the valves. For each valve studied, a series of molds were made under varied pressures (20 mm Hg, 40, 60, 80, 100 and 120 mm Hg), to represent the valve's surface under different pressures. This was necessary for the stress-strain analysis.

The size of the molds (10-30 mm in diameter) and the complexity of the surfaces precluded the use of direct measurements to determine the geometry of the molds. Hence photogrammetry was chosen as a vehicle for the assessment of the topography of the molds, through the following outputs: a) digital models, b) surface profiles, c) contour maps. An accuracy (maximum standard deviation) of at most ± 0.3 mm in the spatial coordinates of surface points was considered adequate for the purposes in which these outputs were to be used.

2. DESCRIPTION OF THE PHOTOGRAMMETRIC SYSTEM USED

2.1. PREPARATORY STEPS

2.1.1. Object-Space Control

To provide basic object-space control, a 3x3x3 inches control object composed of three mutually perpendicular and precision-machined aluminum plates of 1/8 inches thickness (Fig. 3) was used. A 6x6 orthogonal matrix of 36 tiny holes of some 0.02 inches diameter were precision drilled in the surface of each of the three planes, filled with a mixture of glue and dye. The three lines of intersection of the three planes were adopted as object-space coordinates (X,Y,Z) axes,

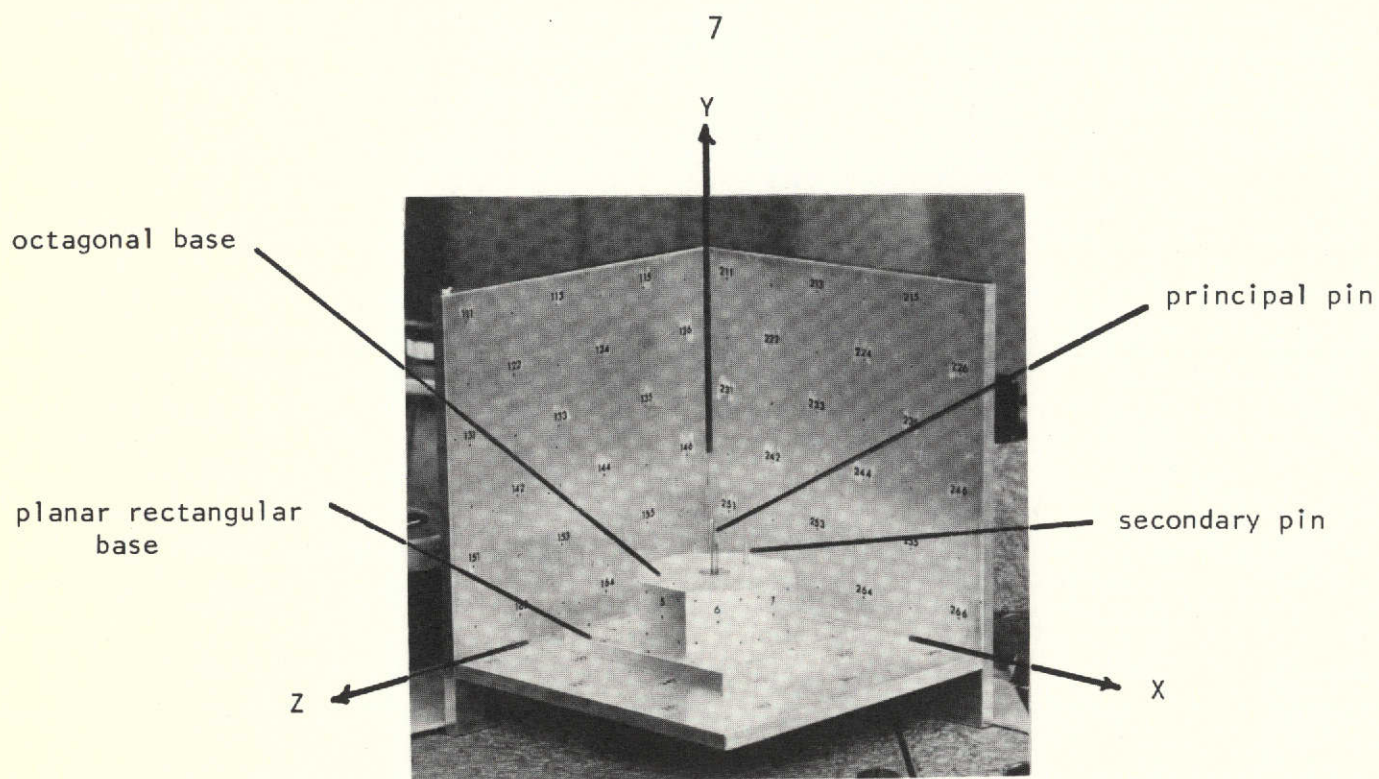


Fig. 3 - Object-Space Control, with Object-Space Coordinate Axes (X,Y,Z)

with their common intersection point as origin. The increments in X,Y and Z for all points drilled on the surfaces of the three mutually perpendicular planes were 0.5 ± 0.005 inches. The thusly obtained spatial coordinates of the control points were used as a basis for the spatial transformation outlined in Sect. 2.3.

The flatness of the three mutually perpendicular planes was reported as being well within ± 0.01 mm. No special tests were conducted to verify this tolerance, in view of the relatively relaxed accuracy requirements of the project (mentioned in Sect. 1).

The orthogonality of the three planes was controlled by a series of tiny holes drilled parallel to the X, Y and Z axes of the control object. Every possible care was taken in assembling the three mutually orthogonal aluminum plates, but in view of the relatively liberal accuracy requirements of the project, no special tests were conducted to verify the orthogonality of the planes, beyond the checks conducted in the machine shop. As will be explained in Sect. 2.4, a test was conducted to assess the overall absolute accuracy of the entire process used in this project, and the results obtained (reflecting the errors associated with the object-space control as well as the errors involved in the photogrammetric process) were well within the specified accuracy requirements.

The molds were affixed to an octagonal base rigidly mounted on a planar rectangular base which could be rotated around an axis (principal pin in Fig. 3). The planar base could be held fixed in any desired orientation in the X-Z plane. Tiny holes, similar to the ones drilled in the surface of the three mutually perpendicular planes, were drilled in the surfaces of the octagonal base and the planar rectangular base.

The molds were held in position on the top of the octagonal base using the two pins visible in Fig. 3. This arrangement enabled the rotation of the mold relative to the fixed control point system. The dots on the rotatable parts were used to correlate the stereo-pairs of the mold taken in various orientations, as explained in Sect. 2.3.3.

2.1.2. Surface Contrast

As mentioned earlier, the molds were formed of a silicone rubber material. Some molds were off-white and others were pastel blue in color, providing no surface contrast.

To provide the surface contrast necessary for the photogrammetric process, several approaches were tried out and the approach deemed most suitable for this project consisted of inserting a dense network of tiny black ink dots on the surface of the molds. Even though randomly positioned dots would have fully satisfied the photogrammetric requirements, it was decided to place the dots along profiles (Fig. 4) to facilitate the comparison of the results from one mold to another and to guide the instrument operator in the data reduction phase in systematically identifying and observing all visible image points.

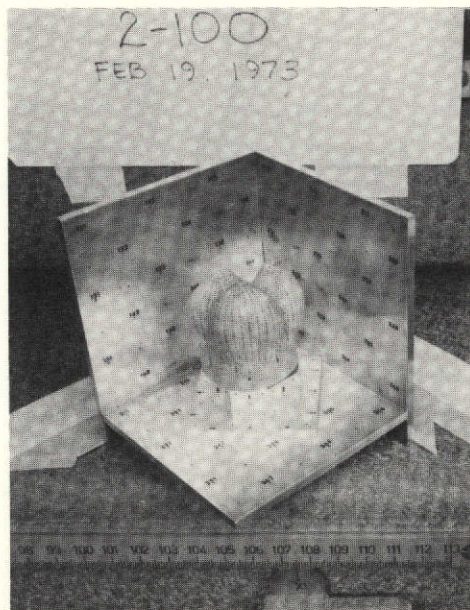


Fig. 4 - A Heart-Valve Mold, With Its Surface Processed, Mounted in the Control Object

In the early stages of the project, a Wild A7 autograph was used to locate the dots on the mold surface. Using a Rapidigraph #00 pen mounted on the Z carriage of the A7 (Fig. 5), tiny ink dots were painstakingly placed along profiles on the mold. Dots were also placed along identifiable boundaries on the mold surface. The use of the A7 in this phase provided a unique vehicle for the assessment of the absolute accuracy of the total operational system as mentioned in Sect. 2.4.

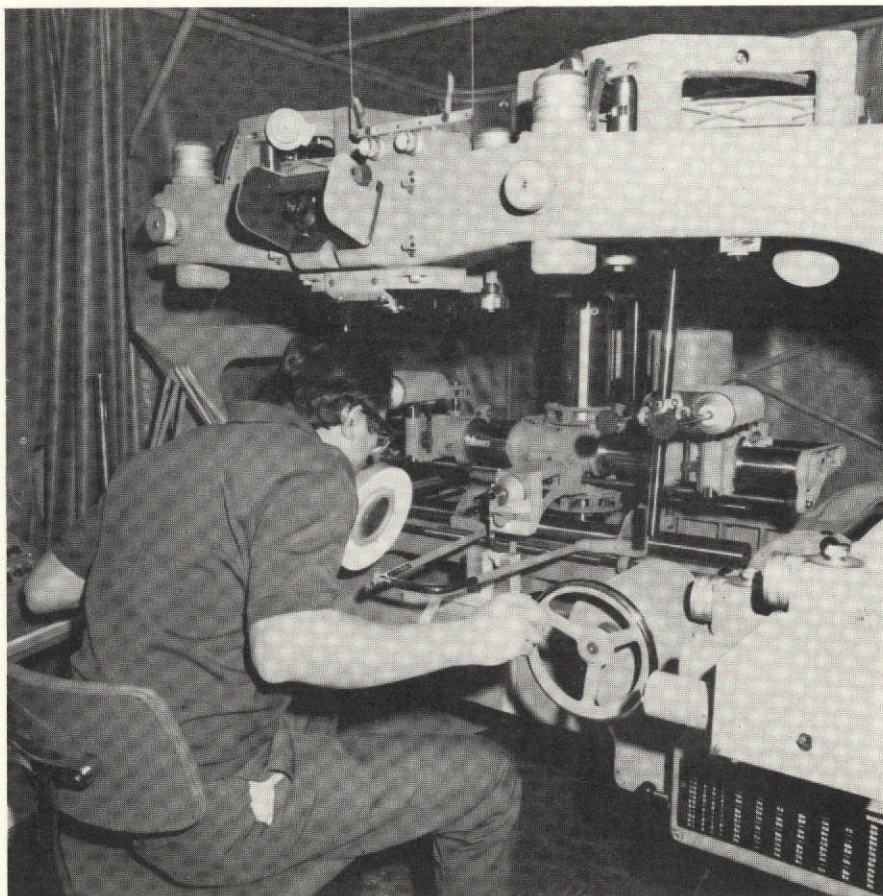


Fig. 5 - Placing Dots on the Mold Surface Using a Wild A7 Autograph

To relieve the A7 from this operation, a simple device (Fig. 6) was designed and manufactured at the University of Illinois. This device allows the positioning and orientation of the molds as desired, for placing dots on the mold's surface using a Rapidograph pen.

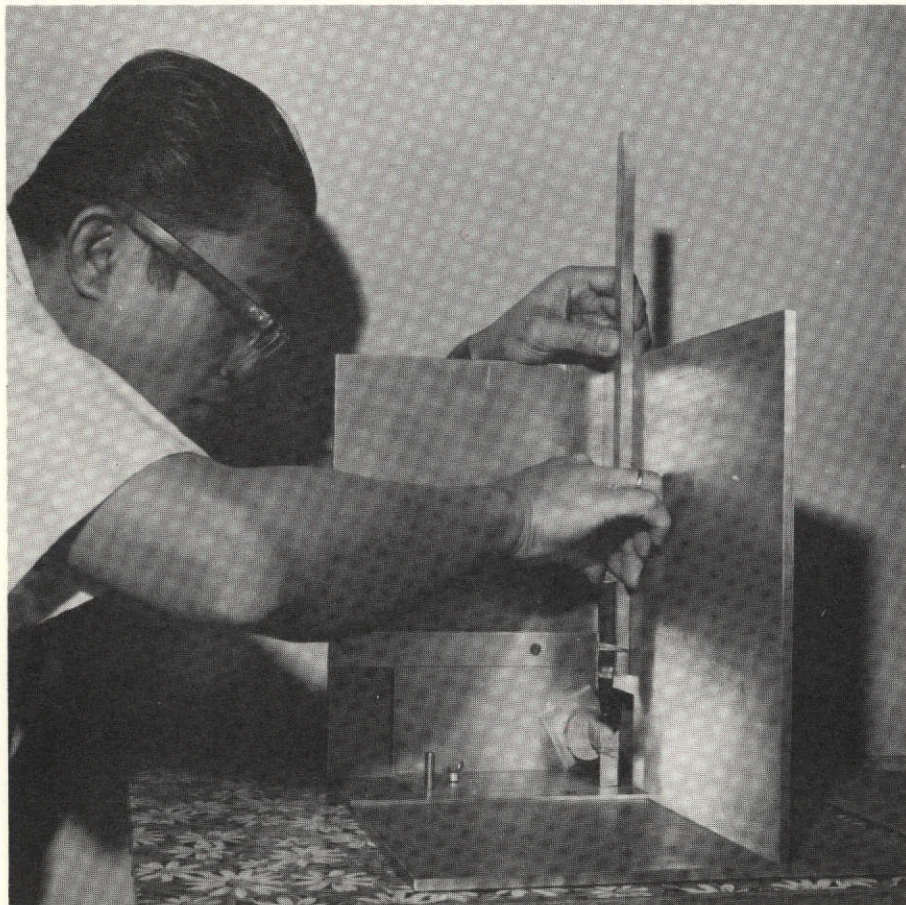


Fig. 6 - Placing Dots on the Mold's Surface Using a "Home-Made" Device

With the dots placed on the mold surface in profiles and along recognizable boundaries, a five-digit identification system was used to identify each dot. These digits identified the leaflet, the profile or boundary, and the point sequence in the profile or boundary.

2.2. DATA ACQUISITION

Because of the small size of the molds and the desirability to work with photographs of as large a scale as possible, it was deemed necessary to use a non-metric camera in view of the focusing flexibility of such cameras. Our group has accumulated considerable experience in the reduction of metric data from non-metric photography (e.g. Ref. 2 and 5) and this was one of the factors that led to the decision to use a non-metric camera for data acquisition in this project.

A Hasselblad 500C camera, image format 55x55 mm, equipped with a Zeiss Planar 50 mm, f/4 wide-angle lens was used. Kodak Tri-X 70 mm film (ASA 400) was utilized.

Stereopairs of photography were taken according to the Normal-Case of Photogrammetry, or approximately so, with the camera axes parallel and approximately perpendicular to the base. This was accomplished by keeping the camera stationary and moving the control object containing the heart valve mold after the first of the two photographs of the stereopair was taken.

The control object, with the mold mounted in it, was placed on one of the carriages of a Wild STK stereocomparator. The camera was

positioned with its axis approximately perpendicular to the direction of the X-translation of the stereocomparator, with a depression angle of some 20° - 30° . The second photograph of each stereopair was taken after the STK carriage was translated in X after the first photograph was taken. Fig. 7 shows the data acquisition setup, while Fig. 8 gives a schematic diagram of the setup. Base-to-Distance ($B:D$) ratio was approximately 1:2. The displacement (B) of the object was precisely measured (difference between X readings of the stereocomparator's carriage) and used as input in data reduction.

In some of the tri-leaflet molds studied in the early stages of the project, only one of the three leaflets (leaflet A) was measured. The other two leaflets were carefully removed from the mold using a sharp knife, to enable the study of the coaption area of the leaflet of interest. In such cases, four oblique sideview stereopairs were taken (Fig. 9). The rotatable base, on which the leaflet was mounted, was rotated some 90° between successive stereopairs, to provide full stereo-coverage of the entire leaflet.

In a few early molds, the geometry of the whole mold was studied. In such cases, seven stereopairs were involved, six oblique sideview stereopairs (Fig. 10) and a topview stereopair. For the topview stereopair, the planar base of the control object was placed at some 45° to the XY, YZ and XZ planes, as illustrated in Fig. 12.

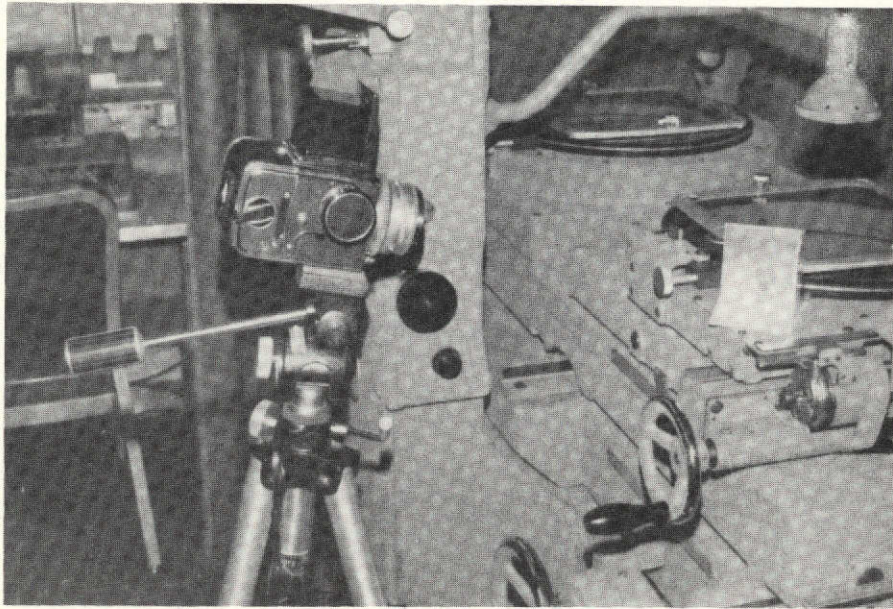


Fig. 7 - Data Acquisition Setup

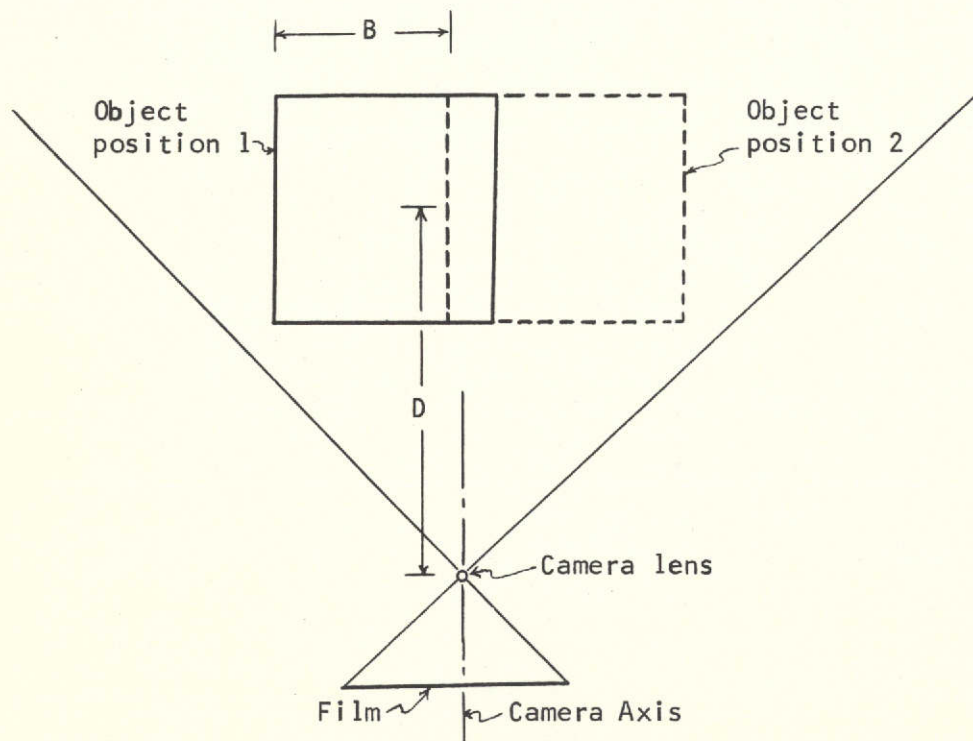


Fig. 8 - Schematic Diagram of Data Acquisition Setup

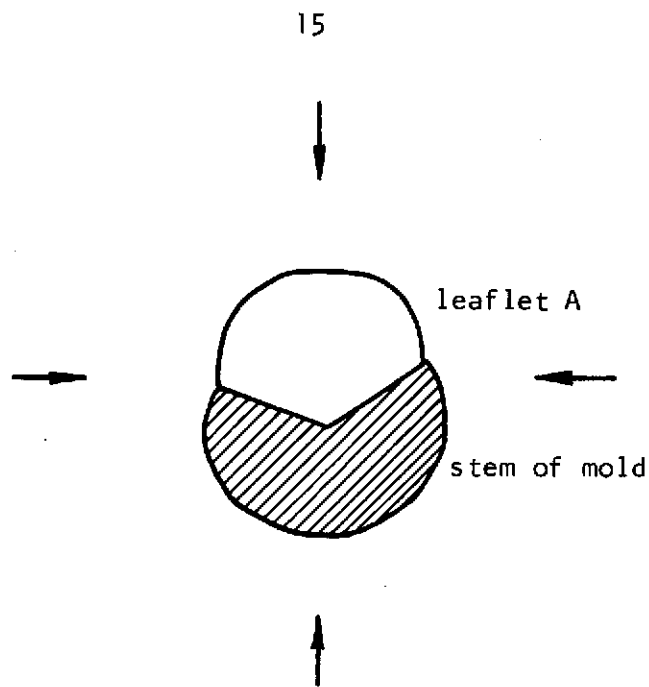


Fig. 9 - Direction of the Four Oblique Sideview Stereopairs to Study an Individual Leaflet (leaflet A) of a Tri-Leaflet Mold

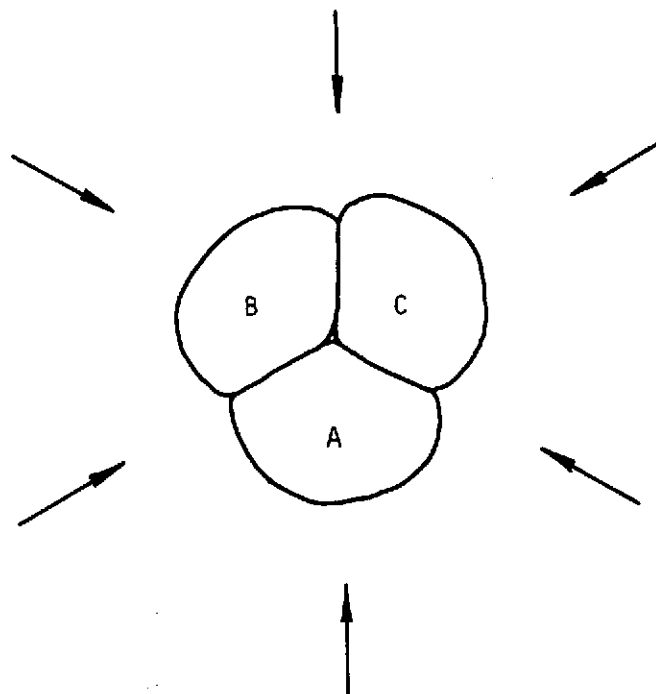


Fig. 10 - Direction of the Six Oblique Sideview Stereopairs to Study Whole Tri-Leaflet Molds in the Early Stages of the Project

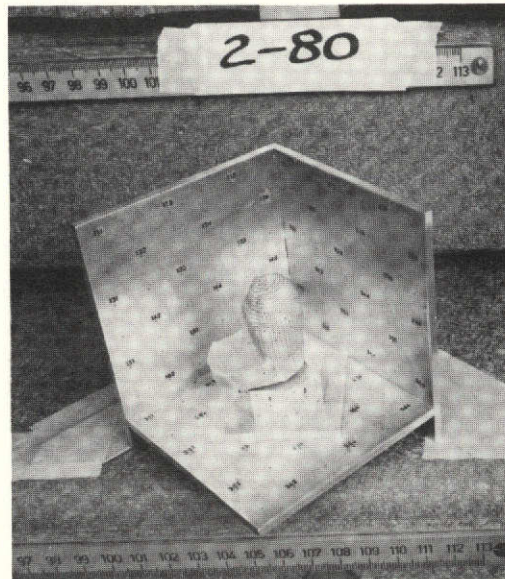


Fig. 11 - A Reproduction of a Part of One of the Photographs of One of the Four Oblique Sideview Stereopairs for Leaflet A of One of the Molds

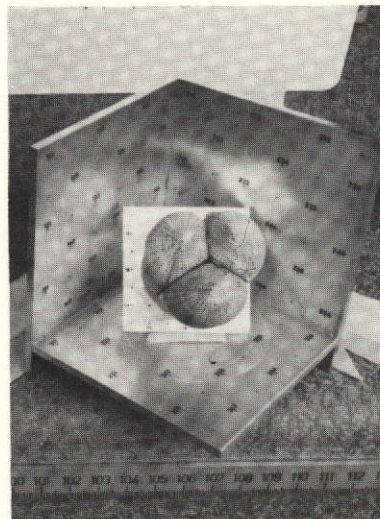


Fig. 12 - A Reproduction of a Part of One of the Photographs of the Topview Stereopair of a Tri-Leaflet Mold

For most molds, however, each of the three leaflets was studied as a separate unit and the tri-leaflet mold was also studied as a whole. To accomplish this, the three leaflets were carefully separated from each other and their surfaces were processed as explained earlier. For each leaflet, four oblique sideview stereopairs were taken as outlined earlier and as shown in Figs. 9 and 11. The three leaflets of each mold were then carefully reassembled and glued together, forming the tri-leaflet mold once again. A topview stereopair was then taken as explained earlier and as illustrated in Fig. 12. Thirteen stereoviews were thus involved in the complete study of each mold.

The films were processed in the regular commercial fashion in a photolab. No special precautions were taken during or after processing. The original negatives were used in the phase of data reduction.

2.3 DATA REDUCTION

During the first year of the project, a Wild A7 autograph was available for use in this project. For the remaining duration of the project, a Wild STK stereocomparator was used for data reduction. With the A7, the semi-analytical approach was used. With the STK, the analytical approach was utilized.

In both cases, observations were made on the original negatives.

2.3.1. Semi-Analytical Reduction

An approximate principal point of each photo was determined as the intersection of the two diagonals of the photo format. A principal

distance of 100 mm was used, resulting in an affine model in the A7. Relative orientation was accomplished using κ' , κ'' and b_z' . The base (B) measured by the displacement of the STK carriage was introduced in the autograph. All visible images of control points and inserted surface dots were observed, three times each, and their model coordinates x, y, z recorded. At the same time, a plot of all points observed was obtained using the A7 plotting capability.

The relationship between object-space coordinates of any point and its observed model coordinates (in the A7 machine coordinate system) can be expressed through the following transformation equation:

$$\begin{bmatrix} X \\ Y \\ Z \end{bmatrix} = \begin{bmatrix} m_{11} & m_{12} & m_{13} \\ m_{21} & m_{22} & m_{23} \\ m_{31} & m_{32} & m_{33} \end{bmatrix} \begin{bmatrix} \lambda_x \cdot x \\ \lambda_y \cdot y \\ \lambda_z \cdot z \end{bmatrix} + \begin{bmatrix} m_{14} \\ m_{24} \\ m_{34} \end{bmatrix} \quad (1)$$

where: X, Y, Z = object-space coordinates of a point,

x, y, z = observed stereomodel coordinates of the same point,

m_{11} through m_{34} = elements of rotations and translations of absolute orientation

$\lambda_x, \lambda_y, \lambda_z$ = scale factors, considering the affine nature of the model

Equation 1 can be rewritten as

$$\begin{bmatrix} X \\ Y \\ Z \end{bmatrix} = \begin{bmatrix} a_{11} & a_{12} & a_{13} \\ a_{21} & a_{22} & a_{23} \\ a_{31} & a_{32} & a_{33} \end{bmatrix} \begin{bmatrix} x \\ y \\ z \end{bmatrix} + \begin{bmatrix} a_{14} \\ a_{24} \\ a_{34} \end{bmatrix} \quad (2)$$

where a_{11} through a_{34} are the parameters of transformation from observed stereomodel coordinates (x,y,z) into object-space coordinates (X,Y,Z) . Equation 2 involves 12 transformation parameters. Four control points are necessary for a unique solution of the 12 transformation unknowns. Using all the control points that were observed in a stereomodel, one obtained a strong least-squares solution for the transformation parameters. Through these 12 transformation parameters, the model coordinates of each observed point on the mold's surface were then transformed into the stereopair's object-space coordinate system, thus providing a partial digital model referred to that stereopair's object-space coordinate system. Further transformations were undertaken to obtain a complete digital model of each of the leaflets and of the mold, referred to a unique global coordinate system. These steps are discussed in Sect. 2.3.3., since they were performed in conjunction with both the semi-analytical and the analytical reductions.

2.3.2. Analytical Reduction

The Direct Linear Transformation (DLT) approach (1) was utilized to establish the relationship between the observed comparator coordinates and the object-space coordinates of the points. The following equations were used for this transformation. It should be noted that only the

linear components of the film deformation and lens distortion are compensated for in the DLT equations used:

$$\left. \begin{aligned} x &= \frac{l_1 X + l_2 Y + l_3 Z + l_4}{l_9 X + l_{10} Y + l_{11} Z + 1} \\ y &= \frac{l_5 X + l_6 Y + l_7 Z + l_8}{l_9 X + l_{10} Y + l_{11} Z + 1} \end{aligned} \right\} \quad (3)$$

where: x, y = comparator coordinates of an image point,

X, Y, Z = object-space coordinates of that point,

l_1 through l_{11} = transformation parameters

For each photograph, eleven transformation unknowns are involved. Using single prime (') for the left photo of a stereopair and double prime (") for the right photo, the following relationships were obtained for each point visible in the stereomodel:

$$\left. \begin{aligned} (l_9' x' - l_1') X + (l_{10}' x' - l_2') Y + (l_{11}' x' - l_3') Z + (x' - l_4') &= 0 \\ (l_9' y' - l_5') X + (l_{10}' y' - l_6') Y + (l_{11}' y' - l_7') Z + (y' - l_8') &= 0 \\ (l_9'' x'' - l_1'') X + (l_{10}'' x'' - l_2'') Y + (l_{11}'' x'' - l_3'') Z + (x'' - l_4'') &= 0 \\ (l_9'' y'' - l_5'') X + (l_{10}'' y'' - l_6'') Y + (l_{11}'' y'' - l_7'') Z + (y'' - l_8'') &= 0 \end{aligned} \right\} \quad (4)$$

From these four equations the object-space coordinates (X, Y, Z) of the observed point were determined.

2.3.3. Further Transformations to Obtain Complete Digital Models of the Individual Leaflets and of the Molds

Since the orientation of the leaflet (to be studied as an independent unit) in the control object was different in each of the four

stereopairs, the transformations outlined in Sects. 2.3.1. and 2.3.2. produced a partial digital model of the leaflet from each stereopair. Each of these four partial models, however, was referred mathematically to a different X,Y,Z object-space coordinate system. To obtain the complete digital model of the leaflet, a further operation was necessary to combine the four partial digital models by referring them to a common coordinate system. A relationship similar to equation 1 was used to accomplish this transformation:

$$\begin{bmatrix} X' \\ Y' \\ Z' \end{bmatrix} = \begin{bmatrix} d_{11} & d_{12} & d_{13} \\ d_{21} & d_{22} & d_{23} \\ d_{31} & d_{32} & d_{33} \end{bmatrix} \begin{bmatrix} X \\ Y \\ Z \end{bmatrix} + \begin{bmatrix} d_{14} \\ d_{24} \\ d_{34} \end{bmatrix} \quad (5)$$

where: X,Y,Z = object-space coordinates of a point referred to the object-space coordinate system of the partial digital model,

X',Y',Z' = object-space coordinates of the same point, referred to the global object-space coordinate system of the total digital model.

d_{11} through d_{34} = transformation parameters

With four partial digital models, the coordinate system of one of them was adopted for the total digital model, and the remaining three partial digital models were transformed into the global coordinate system chosen. A simultaneous least-squares solution was per-

formed. A total of 36 unknowns (transformation parameters), 12 for each of the three partial digital models, were involved in the solution. All common points observed were used in the solution, thus providing a healthy redundancy. This step provided a complete digital model for each of the leaflets, treated as an independent unit.

To obtain a total digital model of the re-assembled tri-leaflet mold, the three complete digital models of the leaflets were transformed into the object-space coordinate system of the topview stereopair. A least-squares solution using an equation similar to equation 2, incorporating all common points, was used. Since no points were common between the individual leaflets, no simultaneous solution was necessary in this phase.

It should be mentioned here that in the early stages of the project, a simple step-by-step solution similar to traversing in surveying, was used to assemble the four partial digital models of each leaflet into a complete digital model of the individual leaflet. Full details about this approach are given in Ref. 6. The simultaneous solution described above was subsequently used in two-thirds of the molds studied in this project. Both approaches yielded essentially the same results and both were fully satisfactory, but the simultaneous solution required less operational time.

2.4. ACCURACY ASPECTS

A test was conducted on one of the molds to assess the overall accuracy of the entire process used in this project. As each ink dot

was inserted on the surface of the mold, its x,y,z coordinates (in the A7 machine coordinate system) were recorded. Thus direct spatial measurements of the mold points were obtained. After transforming these coordinates into the X,Y,Z coordinate system of the total digital model, the direct measurements were compared to the photogrammetrically deduced coordinates. Twenty-three (23) randomly selected points yielded the following results:

Standard deviations: $\sigma_X = 0.10$ mm, $\sigma_Y = 0.06$ mm, $\sigma_Z = 0.05$ mm

Median of differences: in X = 0.08 mm, in Y = 0.02 mm, in Z = 0.02 mm

These figures, which reflect the errors associated with the control points as well as the errors involved in the photogrammetric process, indicated that the accuracy achieved was well within the level specified for the project (maximum standard deviation of at most ± 0.3 mm in the spatial coordinates of mold points).

Of interest also is a comparison between independent plots of a profile in one of the molds (mold 100 in Series 2), obtained from independent measurements made by two operators, each using stereoviews taken on different dates (Fig. 13).

2.5 OUTPUTS

The photogrammetric outputs provided to the Structural Group were as follows:

a) Digital models of individual leaflets and/or of the whole mold, as required,

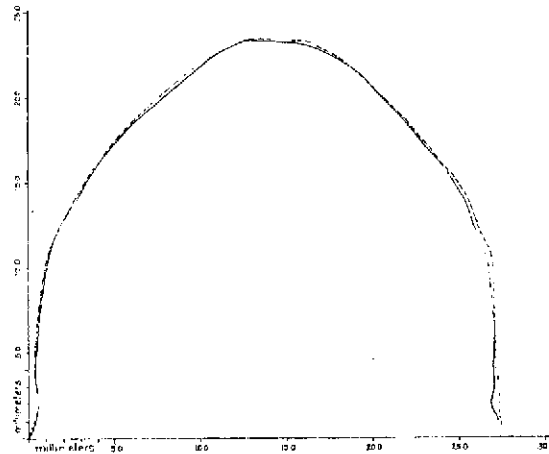


Fig. 13 - Two Independent Plots of a Profile in Mold 100 in Series 2, Deduced from Observations made by Two Operators, Each Using Stereoviews Taken on Different Dates

————— photography taken on October 9, 1972
 ----- photography taken on February 19, 1973

b) Sketch plans (Fig. 14) used to aid the users of the photogrammetric outputs in locating the various points in the digital models.

c) Profiles (Fig. 15). These were cal-comp produced on the basis of the spatial coordinates of the digital model.

d) Contour maps (Fig. 16) were not produced for each mold, but were made upon request in a few cases. These maps were constructed on the basis of the spatial coordinates of the digital model.

e) Dimensions of the coaption area: along each profile,

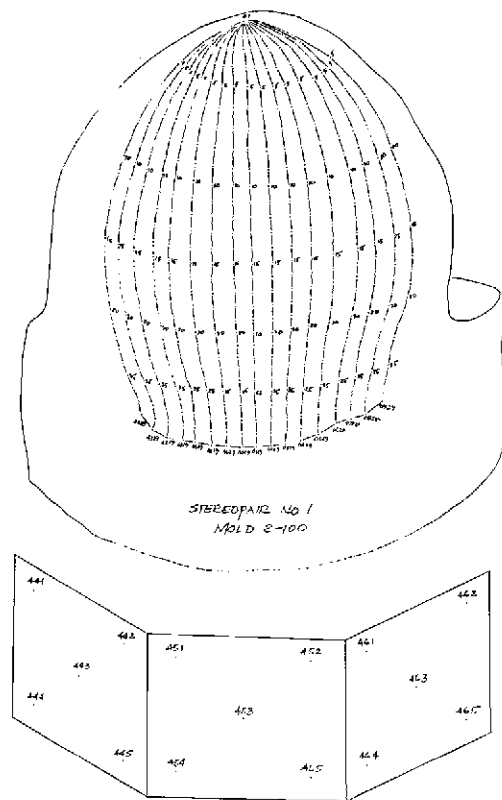


Fig. 14 - Sketch Plan of Mold and Octagonal Base Points Observed in One of the Sideview Stereomodels of Leaflet A of Mold 100 in Series 2

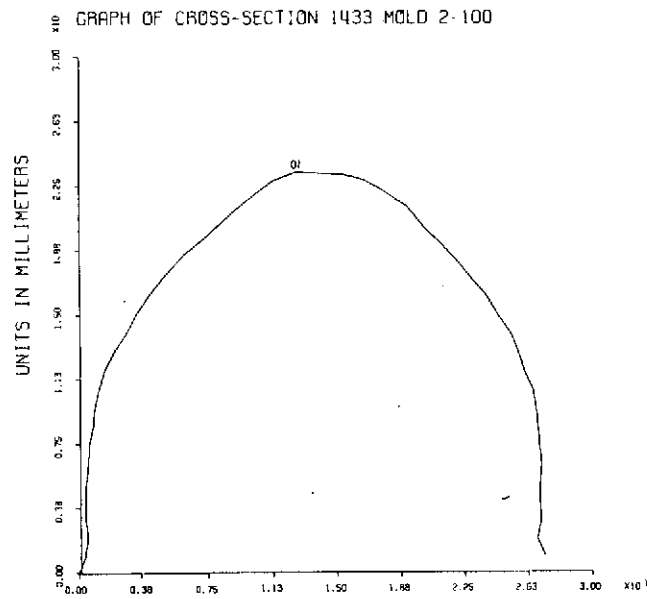


Fig. 15 - A Profile in Mold 100 in Series 2

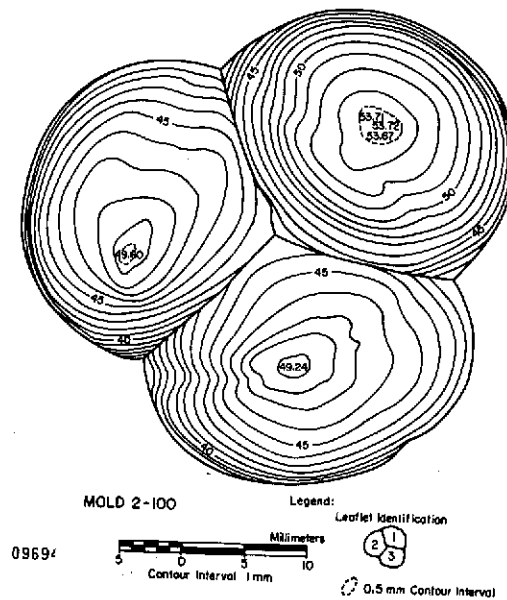


Fig. 16 - A Contour Map of the Top Portion of Mold 100, Series 2.
Spot Elevations are Given Where Necessary.

spatial distances in the coaption area, as indicated in Fig. 17, were deduced from the coordinates provided in the digital model.

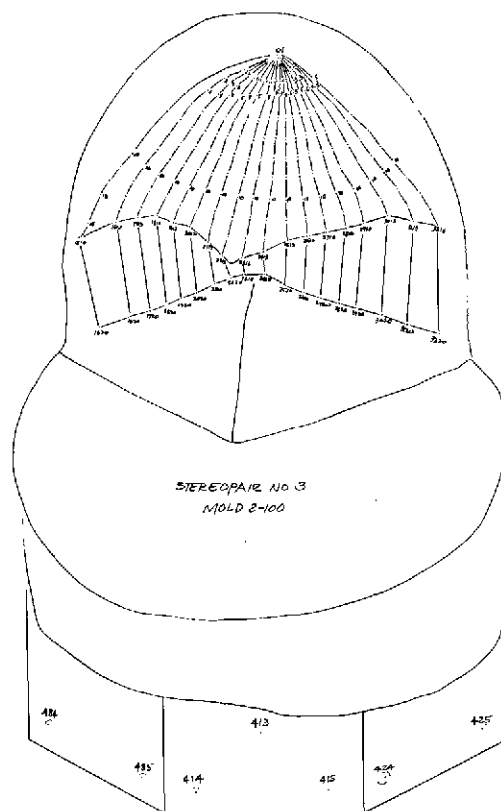


Fig. 17 - Sketch Plan of the Coaption Area of Leaflet A of Mold 100 in Series 2, Showing the End Points of Vectors in the Coaption Area (e.g. 3214-3220, 1614-1620, 2213-2220, etc.)

3. CONCLUDING REMARKS

Based on the photogrammetric outputs provided for three series of molds (total of 18 molds), stress analysis was conducted by the structural group using a thin shell finite element model. The design and manufacture of the prosthetic valve is being undertaken on the basis of the results of the stress analysis and the corresponding strength provisions, on the geometry and dimensions provided photogrammetrically, as well as on inputs provided by the various other studies involved in this project, as indicated in the introduction. It is expected to have a usable valve ready for testing in primates early in 1975.

Further series of molds need to be measured to determine the geometry of a variety of human valves such that the biologic spectrum is sufficiently bracketed. Also, when the prototype of the prosthetic valve becomes available, its geometry needs to be evaluated to compare design and performance data and to aid in further refinement of the prosthetic valve.

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Abbreviations used:

SPIE: Society of Photo-Optical Instrumentation Engineers

ASP: American Society of Photogrammetry

UI: University of Illinois at Urbana-Champaign

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